

(b) in the brochure entitled "The Clinical Importance of Weight Reduction in Exogenous Obesity" the drug was offered for diabetes, arteriosclerotic heart disease, hypertension, and ulcers;

which labeling representations differed materially from the labeling claims permitted by the effective new drug application.

DISPOSITION: 10-13-61. Default—destruction.

#### DRUG FOR VETERINARY USE

**6744. Iro-Jex injectable.** (F.D.C. No. 45628. S. Nos. 61-044/45 R.)

QUANTITY: 226 30-cc. btls. and 607 100-cc. btls. at Kansas City, Mo.

SHIPPED: 2-7-61 and 3-22-61, from Los Angeles, Calif.

LABEL IN PART: "Iro-Jex Injectable Iron-Arsenic Solution each 2 cc contains: Ferric Cacodylate 1 Gr. Copper Sulfate 1/100 Gr. \* \* \* Suggested dosage: 2 cc given intramuscularly or intravenously—distributed by the National Laboratories Corp. Kansas City."

RESULTS OF INVESTIGATION: When shipped, the labeling offered the drug for human use. The dealer relabeled the article for veterinary use.

LIBELED: On or about 4-17-61, W. Dist. Mo.; amended libel on or about 5-17-61.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 7-12-61. Default—destruction.

#### DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

**6745. Vigo Forte tablets, Altocaps capsules, and vitamin B<sub>12</sub> and B<sub>1</sub> injection.** (F.D.C. No. 45900. S. Nos. 32-274/77 R.)

QUANTITY: 19 50-tablet btls. of *Vigo Forte tablets*; 18 20-capsule btls. of 50-mg. *Altocaps capsules*; 20 20-capsule btls. of 100-mg. *Altocaps capsules*; and 79 10-cc. vials of *vitamin B<sub>12</sub> and B<sub>1</sub> injection*, at San Juan, P.R.

SHIPPED: Between 10-1-60 and 11-17-60, from Newark, N.J., by Benson Pharmacal Corp.

LABEL IN PART: (Btl.) "Vigo Forte \* \* \* Testosterona 2 mgm. Vitamin E 10 mgm. Extracto de damiana 60 mgm. Extracto de nucz vomica 5 mgm. Clorhidrato de yohimbine 5 mgm. Puerto Rico Drug \* \* \* San Juan, P.R.—Distributors"; "Benson Altocaps 50 Mg. [or "100 Mg."] Each capsule contains \* \* \* Vitamin E (from d-alpha Tocopheryl Acetate Concentrate, N.F.) Directions: One to six capsules daily \* \* \* Benson Pharmacal Co., Inc., New York, N.Y."; and (vial) "Multiples Dosis 10 cc Frasco Vitaminas B<sub>12</sub> y B<sub>1</sub> Cada cc contiene vitamina B<sub>12</sub> 1000 mcgm. Vitamina B<sub>1</sub> 100 mg. \* \* \* intramuscular Benson Pharmacal Corp., Newark, N.J."

LIBELED: 5-29-61, Dist. P.R.

CHARGE: *Altocaps capsules*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for habitual abortion, ovarian failure, muscular dystrophy, and amyotrophic lateral sclerosis.

*Vigo Forte tablets and vitamin B<sub>12</sub> and B<sub>1</sub> injection*, 503(b) (4)—the articles were drugs subject to the provisions of 503(b) (1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without a prescription."

DISPOSITION: 7-20-61. Default—destruction.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR  
ADEQUATE DIRECTIONS OR WARNING STATEMENTS .**

**DRUGS FOR HUMAN USE\***

**6746. Insta-Pep tablets.** (F.D.C. No. 43373. S. No. 82-806 P.)

QUANTITY: 17 cases of 36 50-tablet btls. and 10 cases of 72 25-tablet btls. at North Kansas City, Mo., in possession of Katz Drug Co.

SHIPPED: Between 6-24-59 and 8-26-59, from New York, N.Y., by Drug Research Corp.

LABEL IN PART: "Insta-Pep with Dynamol and 'Vitamin Feed' for prolonged Vitamin-Mineral Release A high potency therapeutic Vitamin-Iron formula \* \* \* Each tablet contains: Thiamine Chloride (Vit. B<sub>1</sub>) 15.0 mg. Riboflavin (Vit. B<sub>2</sub>) 6.0 mg. Cobalamin Concentrate (Vit. B<sub>12</sub> Activity) 3.0 mg. Nicotinic Acid 30.0 mg. \*Calcium Pantothenate 3.0 mg. \*Choline Bitartrate 10.0 mg. Folic Acid 0.1 mg. \*Inositol 20.0 mg. \*dl-Methionine 20.0 mg. Iron (from Ferrous Sulfate) 30.0 mg. Ascorbic Acid (Vit. C) 90.0 mg. Pyridoxine Hydrochloride (Vit. B<sub>6</sub>) 0.5 mg. Whole Liver Desiccate 25.0 mg. Calcium (from Dicalcium Phosphate) 30.0 mg. Phosphorus (from Dicalcium Phosphate) 20.0 mg. Sodium Acid Phosphate 100.0 mg. \*Vitamin E (from d-alpha Tocopheryl Acid Succinate) 1.0 I.U. Iodine (from Potassium Iodide) 0.1 mg. Copper (from Cupric Sulfate) 1.25 mg. \*Manganese (from Manganese Sulfate) 0.85 mg. \*Cobalt (from Cobalt Sulfate) 0.04 mg. Potassium (from Potassium Sulfate) 0.65 mg. Magnesium (from Magnesium Sulfate) 0.50 mg. together with factors natural to liver content Caffeine Alkaloid Anhydrous 3.0 gr. Sole Distributors: Drug Research Corp. New York, N.Y."

ACCOMPANYING LABELING: Newspaper tear sheet, reading in part "Insta-Pep Stops Rapid Vitamin-Mineral Loss in Your Body! Fights Fatigue in 20 minutes! The Kansas City Star, Sunday, August 2, 1959."

RESULTS OF INVESTIGATION: The newspaper tear sheets were displayed with the article at various Katz Drug Stores in Kansas City, Mo.

LIBELED: 9-25-59, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was capable of providing instant pep; was the first new development in the vitamin field in over 20 years; stopped rapid vitamin-mineral loss in the body; fought fatigue in 20 minutes; stopped "vitamin let-down" even if tense, worried, or working under pressure; that feeling of fatigue as a result of tensions, worry and working under pressure is due to "vitamin let-down"; that chronic fatigue not aided by other vitamin preparations would be aided by *Insta-Pep tablets* to the extent that users would never feel tired any more; that *Insta-Pep tablets* contained a new, remarkable, amazing antifatigue factor; that "Dynamol" was a new "Vitamin-Mineral" discovery; that *Insta-Pep tablets* contained all necessary vitamins-minerals to build up the body; that the body throws off

\*See also No. 6743.